UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO COMPEL DISCOVERY AND IN SUPPORT OF PLAINTIFFS' PROPOSED CMO NO. 7

I. INTRODUCTION

This memorandum addresses plaintiffs' position as to a proper case management order to govern the period between the present and this Court's ruling on motions to dismiss the Amended Master Consolidated Complaint ("AMCC"). The parties' most significant dispute in this regard involves the scope of discovery. Resolution of this issue will determine if meaningful discovery will occur now pursuant to plaintiffs' position, or whether virtually no discovery will move forward as defendants would have it under defendants' proposed CMO. This Court twice recently directed the parties to commence discovery. On May 13, 2003, this Court ordered that "[d]iscovery shall begin forthwith on the pending non-dismissed claims." (May 13, 2003 Order, at 47.) On June 18, 2003, this Court again directed the parties to proceed with discovery in

earnest as against all non-dismissed claims and all non-dismissed defendants. (June 18, 2003 status conference, transcript unavailable.)

Pursuant to the Court's direction, after the status conference, plaintiffs promptly served requests for production of documents and 30(b)(6) deposition notices on those defendants who, in plaintiffs' view, were not dismissed. This includes any defendant not dismissed from both Class 1 and Class 2 claims. Discovery was thus served on 14 of the defendants in the AMCC.

Shortly thereafter, 12 of the 14 defendants (upon whom discovery was served) responded by taking the position that they were not subject to discovery. According to the resisting defendants, discovery could go forward only on brand name drugs for which a specific plaintiff purchaser was identified in the Master Consolidated Complaint ("MCC"). Thus, under the resisting defendants' position discovery would be limited to a production by only 4 defendants for roughly 7 drugs. In effect, no meaningful discovery would occur and the litigation would be at a standstill until after a ruling on the motions to dismiss the AMCC; given the briefing schedule, that ruling will likely not be issued until some time after January 2004. Document production from the resisting defendants would thus not begin until March 2004, or later. Plaintiffs believe this virtual stay of discovery is not what the Court envisioned when it ordered discovery to proceed.

In Plaintiffs' Proposed CMO No. 7, plaintiffs submit two alternate discovery proposals to the Court. Under Proposal A, plaintiffs propose that discovery should be permitted of all defendants who were not dismissed as to both the Class 1 and Class 2 claims and the scope of discovery should include: (i) drugs identified in the defendant-specific allegations of the MCC (pp. 44-85), (ii) that were identified in the defendant-specific allegations of the AMCC (pp. 50-183), and (iii) with respect to which a plaintiff has been identified in the AMCC as having

purchased a drug from that defendant. As the Court has noted, there is no question that claims will go forward in this case. And, given the details in the AMCC, there is little question that claims will go forward on all of these drugs identified in the defendant-specific sections of the MCC and AMCC. Under Proposal A, discovery would proceed against 14 defendants and the scope of that discovery would cover 81 drugs.

Under Proposal B, the 14 defendants would produce discovery on all drugs identified in the defendant-specific sections of the AMCC (pp. 50-183). This section of the AMCC contains an expanded list of inflated drugs with specific allegations. This would expand the scope of production to cover 116 drugs. As explained below, the AMCC provides detailed allegations as to the specific circumstances of AWP manipulation and plaintiffs believe that such specificity warrants production as to these drugs now since the claims will be going forward against these defendants.

Further, many of the defendants have again received a subpoena from the government and will be producing information on the issues raised by the MCC and AMCC which would also be responsive to the discovery requests served by plaintiffs. Production of such material now would advance the litigation and is also consistent with the Court's prior order requiring the production of documents produced to the government. Thus, plaintiffs' CMO contemplates that discovery would include these documents.

Finally, plaintiffs' CMO proposes that the parties begin working on class certification so that the issue will be fully briefed by June 2004. Defendants on the other hand propose that the class certification process should take 18 months and not begin until after the ruling on the motion to dismiss the AMCC. This would unduly delay this litigation.

II. FACTS[1]

On May 13, 2003, this Court issued a Memorandum and Order on pending Rule 12(b)(6) motions ("Order"). *See* Affidavit of Thomas M. Sobol ("Sobol Aff."), Ex. 1. In this 48 page Order, the Court, among other things: (i) dismissed the RICO counts (Counts I-IV), (ii) left standing the consumer protection and declaratory relief counts (Counts V-VII), (iii) allowed the motion to dismiss with respect to new drugs that had not been identified by "name of the drug and the allegedly fraudulent AWP," and (iv) ordered that "discovery shall begin forthwith on the pending non-dismissed claims." The Order specified the defendants against whom both Class 1 and Class 2 claims were dismissed. The dismissals were "without prejudice to a motion to amend to cure any defects." *Id.*

On June 12, 2003, plaintiffs filed a motion to amend along with an Amended Master Consolidated Class Action Complaint (the "AMCC"). The AMCC sets forth claims against 22 manufacturer business groups, contains both general and specific allegations against those defendants (in 301 pages containing 741 paragraphs of allegations), and includes two appendices specifying for each defendant the average wholesale price inflated drugs ("AWPIDs").

On June 18, 2003, this Court held a status conference. At the conference, the Court allowed the motion to amend and ordered a schedule for anticipated Rule 12(b)(6) motions on the AMCC. The Court also indicated that discovery should proceed as to all non-dismissed claims and non-dismissed defendants; that discovery should not proceed on the Together Rx conspiracy claims, and, that the scope of such discovery be fairly drawn in a manner so as not to frustrate the progress of discovery. Sobol Aff. at ¶ 4 (transcript unavailable).

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[1] The facts for this motion are supported by the Affidavit of Thomas M. Sobol, submitted herewith. That affidavit attaches the relevant documents and correspondence. (References appear as "Sobol Aff., ¶ __, Ex. __.)

On June 19 and 20, 2003, plaintiffs issued a set of document requests and deposition notices in order to conform with the directions of the Court at the June 18, 2003 status conference. Sobol Aff., Exs. 2, 3, and 4. The document requests seek production from only 14 defendants. These requests were directed to those defendants not dismissed in both the Class 1 and Class 2 claims. The Rule 30(b)(6) deposition notices were issued against the same defendants, with the exception of the Boehringer Group and B. Braun. Sobol Aff. Ex. 4.[2] However, in late June 2003, 12 of the manufacturers communicated their view, that each have been dismissed from the original MCC and accordingly were under no obligation to provide any discovery whatsoever. Sobol Aff. at 5. The other 2 sought to narrow the scope of discovery. Sobol Aff. at 5.

On June 26, 2003, plaintiffs provided a proposed CMO. Sobol Aff. Exs. 5 and 6. Thereafter, a series of teleconferences were conducted with numerous defendants in an effort to resolve the discovery disputes which in turn are at the heart of the disputes over the CMO.

On July 3, 2003, plaintiffs sent a letter to all defense counsel setting forth a proposal for a narrower scope of discovery against each of the defendants identified who received the revised document request and deposition notice. *Id.* Ex. 7. Numerous defendants had taken the position (in response to comments from this Court at the June 18, 2003 hearing) that there should be no discovery beyond the non-dismissed claims in the original MCC, and they took that to mean (among other things) that no discovery should be had against any defendant unless a specific

[2] In the AMCC, there are 22 defendant manufacturers or manufacturer groups, along with Together Rx, LLC. Five of the 22 manufacturers were ostensibly dismissed as to both Class 1 and Class 2 claims, and those defendants are not included in the revised document request and deposition notices. Two defendants in the AMCC were not named defendants in the original MCC, and therefore they are not included in the revised document request and deposition notices. As to one, Johnson & Johnson, clarification will be sought if no resolution can be reached. See Exhibit A attached hereto.

drug and inflated AWP had been set forth in the original MCC.[3] To accommodate this position, plaintiffs proposed to narrow discovery as to those drugs that ***both*** had been specifically named in the original MCC and which also appear in the text of the AMCC detailing examples of AWP manipulation.

Since making the July 3, 2003 proposal, plaintiffs have been able to resolve a narrow scope of discovery for 3 of the defendant manufacturers. The remaining defendants all take the position that they are under no obligation to provide meaningful discovery at this procedural stage. The differences in the scope of discovery under each proposal are summarized in the chart attached as Exhibit A. Under defendants' interpretation of the proper scope of discovery most of the defendants would not produce any documents.

III. PLAINTIFFS' PROPOSED SCOPE OF DISCOVERY IS CONSISTENT WITH THE COURT'S ORDERS

The dispute as to the scope of discovery under CMO No. 7 covers four areas: (1) whether defendants who manufactured multi-source drugs are subject to discovery; (2) whether a defendant must produce discovery if the MCC did not identify a specific plaintiff of that defendant's specified AWPID, but the AMCC does so specify; (3) the scope of discovery as to third-party production; and (4) the production of documents being produced to governmental investigators.

A. Multi-source Drugs Are Subject to Discovery

Defendants Abbott, Aventis Behring, Baxter, Boehringer, Braun, Dey, Fujisawa, Immunex, Pharmacia, Schering Plough and Watson all take the position that they are not subject

[3] In the original MCC, examples of a particular defendants' drugs and inflated AWPs were set forth in the text of the complaint. Plaintiffs had treated that document as a notice pleading, listing, in a non-comprehensive way, examples of inflated drugs. After this Court's May 13, 2000 ruling, the AMCC sets forth a comprehensive listing of all drugs for each defendant along with the allegedly inflated AWP (and this listing appears both in the text of the AMCC and in Appendix A to that document).

to discovery because the only drugs identified in the MCC are multi-source drugs and that the Court intended to dismiss all claims as to such drugs, which in effect, according to these defendants, dismissed them from the case.

All of these defendants are defendants who were not dismissed as to both Class 1 and Class 2 claims, so they remain a defendant as to the claims of one class and as to the declaratory count. Thus, plaintiffs take the position that discovery as to these defendants is proper.

In its order describing the crux of the AWP claims in this case, the Court used as an example, drugs produced by Abbott which are multi-source drugs. For example, when summarizing the key allegations of the MCC, the Court stated:

> The pharmaceutical companies vastly overstate the AWP of many drugs in the data they provide to the trade publications. For example, for one drug called "Acyclovir," defendant Abbott Laboratories reports an AWP to the "Red Book" publication of $1047.38, while the actual average wholesale price is only $349.05. In some instances the reported AWP is more than 10,000 percent higher than the actual AWP. The following table, drawn from the complaint (¶ 190), provides just a sampling of AWP overstatements by Abbott.

Order at 6. The table cited by the Court then lists 16 drugs manufactured by Abbott all of which are multi-source drugs. For each of these drugs, the MCC identifies the drug, the AWP and the inflated spread.

Plaintiffs believe that the Court viewed these allegations as an example of an instance where the MCC stated a claim. Abbott was not dismissed with respect to Class 2 claims. Yet Abbott takes the position that it is not subject to discovery because these drugs are multi-source drugs. Given the Court's use of these drugs as an example of how the AWP scheme works, plaintiffs believe the Court did not intend to dismiss this type of drug. This argument is the basis

for most of the resisting defendants' refusal to provide discovery. It applies in addition to Abbott to Aventis Behring, Baxter, Boehringer, Braun, Dey, Fujisawa, and Immunex.

A fair reading of the Court's Order is that these allegations involving a multi-source drug state a claim for relief so long as a plaintiff purchaser is identified and the AWP is also identified. Plaintiffs believe that this is what the Court intended and that discovery can and should proceed against any defendant not dismissed as to both Class 1 and Class 2 claims.

B. Plaintiffs Have Cured the Purchaser Issue

In the Court's Order with respect to the MCC, the Court ruled that the MCC had failed to specify in certain circumstances that a plaintiff had purchased a drug with an inflated AWP from either a specific defendant or which particular drug had been purchased from that defendant. Certain defendants now take the position that even if they are not dismissed from the Class 1 and 2 claims, if the MCC fails to identify a plaintiff who purchased a specific drug from that defendant, then they are in effect dismissed from the case and not subject to discovery. The effect of this interpretation of the scope of discovery is to severely limit the defendants and drugs subject to discovery.

This defect in the MCC was readily cured in the AMCC where plaintiffs have identified a purchaser of an AWP inflated drug from each defendant, and in most instances, a purchaser of each AWP drug that is covered by the AMCC. Given the cure of this issue in the AMCC and the Court's recognition that if a cure occurred a claim would exist, plaintiffs believe that discovery should proceed against any defendant for which a plaintiff is identified in the AMCC as having purchased from that particular defendant.

C. The Scope of Third-Party Production Should Include All Drugs Specified in the AMCC

Plaintiffs and defendants agree that third-party discovery should proceed. The only dispute is the scope of such discovery. Plaintiffs believe that discovery against third-parties should include all drugs in the defendant specific section of the AMCC for any defendant subject to discovery. Again, if one follows defendants' narrow interpretation of the Order, third-party discovery would be allowed as to 4 defendants on fewer then a dozen drugs.

Plaintiffs submit that while the parties are awaiting rulings on the AMCC, a great deal of work can be accomplished by gathering documents from third-parties and that the production should include documents regarding the non-dismissed defendants and that the scope of the drugs covered should include the drugs in either CMO Proposal A (all drugs identified in the defendant specific text section of the MCC, pp. 44-85) or Proposal B (all drugs identified in the defendant specific text sections of the AMCC, pp. 50-183). Proceeding in this fashion will also reduce third-parties from having to repeatedly produce responsive documents.

D. Defendants Should Continue to Produce Documents Also Produced to the Government

This Court has already ordered defendants to produce documents that were collected and produced in response to governmental investigations. Since those productions were completed defendants continue to receive subpoenas from government agencies. For example, on June 26, 2003, Abbott, Aventis, Bristol Meyers, Glaxo, Johnson & Johnson, Pfizer, Schering, and Warrick all received a demand to produce AWP related documents from the United States House of Representatives Committee on Energy and Commerce. *See* Sobol Aff. Ex. 8. That information will have to be gathered and defendants will incur minimal added burden by

producing this same information in this case. The information called for goes to the crux of this litigation. In the opening paragraph, the Committee noted,

> The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursement rates under the Medicare program. In that investigation, the Committee uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for $7.50, when the reported price for Medicare was $740. The taxpayer therefore reimbursed the doctor almost $600 for dispensing the drug and the cancer patient had a $148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.

And, as to the practice of marketing the spread that is discussed in the MCC and AMCC, and in the Order, the Committee called for:

> [T]he period beginning January 1, 1998, to the present, has the spread on any of the subject drugs ever been discussed or considered in relation to purchase, utilization, distribution, marketing, sales or promotion of the subject drugs? If so, please describe such circumstances and produce all records relating to such discussions or considerations. [Sobol Aff. Ex. 8.]

This information is plainly relevant, and many of the drugs that are the subject of the inquiry are multi-source drugs, thus corroborating the MCC and AMCC's focus on such drugs.

IV. THE COURT SHOULD ADOPT OTHER PROVISIONS OF PLAINTIFFS' PROPOSED CMO NO. 7.

In addition to the dispute over the scope of discovery, the parties disagree as to the timing of Plaintiffs' Motion for Class Certification and the process for presenting the motion to the Court.

A. Timing of the Class Certification Motion

Plaintiffs believe that the Court wants this litigation to proceed as promptly as possible given its complexity. Consistent with that goal, plaintiffs propose that the parties proceed to work on certification at once. Plaintiffs' proposal is simple:

Class Certification

1. Any fact discovery the parties feel they need on this issue should be done by December 1, 2003.

2. The identity of any experts to be used on the motion shall be disclosed by December 1, 2003.

3. Additional disclosures of experts responsive to the first disclosure shall be made by January 1, 2004.

4. Expert opinions shall be disclosed by plaintiffs by January 1, 2004.

5. Defendants' disclosure of expert opinion by February 15, 2004.

6. Class Certification Motion due on March 1, 2004.

7. Opposition due May 1, 2004.

8. Reply due June 1, 2004.

This would have the parties briefing this issue perhaps before rulings on the AMCC. But briefing could be supplemented in response to any ruling. By proceeding now, the class motion can be ready for decision 11 months from now.

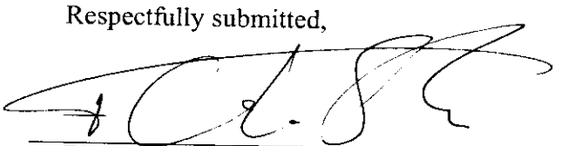
Defendants propose that the issue of class certification would not be addressed until after the ruling on the motions to dismiss the AMCC. That ruling might not occur until February 2004. Under defendants' schedule, plaintiffs' motions would be filed in August 2004 and the briefing schedule conducted February 2005. Defendants would thus stretch out the class certification to 18 months exclusive of the time for the Court to rule. This is an extraordinarily prolonged process.

B. Plaintiffs' Process for the Motion Should Be Adopted

Plaintiffs' proposed process for class certification is to have expert disclosures precede the filing of the motion for class certification. Defendants seek to delay their disclosure until after the motion is filed. Plaintiffs believe that the Court will receive a better presentation if the expert disclosures occur prior to the filing of the motion. Without such disclosure, plaintiffs will be filing their opening motion without notice of the defendants' objections to class certification. This usually results in the plaintiffs anticipating rather than knowing the basis for an opposition, and opening briefs are usually therefore not as focused as they could be. Often this results in the Court receiving briefs that address issues that need not be addressed.

DATED: July 31, 2003

Respectfully submitted,



Thomas M. Sobol
Edward Notargiacomo
Hagens Berman LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Steve W. Berman
Sean R. Matt
Hagens Berman LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

LIAISON AND CO-LEAD COUNSEL

Eugene A. Spector
Jeffrey Kodroff
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Kenneth A. Wexler
Elizabeth Fegan Hartweg
Kenneth A. Wexler & Associates
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

Samuel Heins
Brian Williams
Heins, Mills & Olson, P.C.
700 Northstar East
608 Second Avenue South
Minneapolis, MN 55402
Telephone: (612) 338-4605
Facsimile: (612) 338-4692

CO-LEAD COUNSEL

Michael McShane
Alexander, Hawes & Audet, LLP
300 Montgomery Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 982-1886
Facsimile: (415) 576-1776

Robert E. Piper, Jr.
Piper & Associates
624 Pierre Avenue
Shreveport, LA 71103
Telephone: (318) 226-0826
Facsimile: (318) 424-9900

PLAINTIFFS LEAD COUNSEL COMMITTEE

Anthony Bolognese
Bolognese & Associates
One Penn Center
1617 JFK Boulevard, Suite 650
Philadelphia, PA 19103
Tel: (215) 814-6750
Fax: (215) 814-6764

Jonathan W. Cuneo
The Cuneo Law Group
317 Massachusetts Ave. N.E., Suite 300
Washington, DC 20002
Tel: (202) 789-3960
Fax: (202) 789-1813

Neal Goldstein (Of Counsel)
Freedman & Lorry, PC
400 Market Street, Suit 900
Philadelphia, PA 19106
Tel: (215) 925-8400
Fax: (215) 925-7516

Michael E. Criden
Hanzman & Criden, PA
Commerce Bank Center, Suite 400
220 Alhambra Circle
Coral Gables, FL 33134
Tel: (305) 357-9000
Fax: (305) 357-9050

Blake M. Harper
Kirk B. Hulett
Hulett Harper LLP
550 West C Street, Suite 1700
San Diego, CA 92101
Tel: (619) 338-1133
Fax: (619) 338-1139

Jonathan D. Karmel
Karmel & Gilden
221 N. LaSalle Street
Suite 1414
Chicago, IL 60601
Tel: (312) 641-2910
Fax: (312) 641-0781

Dianne M. Nast
Roda & Nast, PC
801 Estelle Drive
Lancaster, PA 17601
Tel: 717-892-3000
Fax: 717-892-1200

Henry H. Rossbacher
Rossbacher & Associates
811 Wilshire Boulevard, Suite 1650
Los Angeles, CA 90017-2666
Tel: (213) 895-6500
Fax: (213) 895-6161

Jonathan Shub
Sheller, Ludwig & Badey, P.C.
1528 Walnut Street, 3rd Floor
Philadelphia, PA 19102
Tel: (215) 790-7300
Fax: (215) 546-0942

Scott R. Shepherd
Shepherd & Finkleman, LLC
117 Gayley Street, Suite 200
Media, PA 19063
Tel: (610) 891-9880
Fax: (610) 891-9883

Lee Squitieri
Squitieri & Fearon
521 Fifth Avenue, 26th floor
New York, NY 10175
Tel: (646) 487-3049
Fax: (646) 487-3095

Lisa J. Rodriguez
Ira Neil Richards
Trujillo Rodriguez& Richards, LLC
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Tel: (215) 731-9004
Fax: (215) 731-9044

Mitchell A. Toups
Weller, Green, Toups & Terrell, L.L.P.
2615 Calder Street, Suite 400
Beaumont, TX 77704
Tel: (409) 838-0101
Fax: 409-838-6780

Damon Young
Lance Lee
Young, Pickett & Lee
4122 Texas Boulevard
Texarkana, AR/TX 75504
Tel: (903) 794-1303
Fax: 903-792-5098; 903-794-5098

Stephen C. Richman, Esq.
Markowitz & Richman
121 South Broad Street
1100 North America Building
Philadelphia, PA 19107
Telephone: (215) 875-3100